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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,455	11/14/2001	Jiradcj Manosroi	0652.2190001/EKS/Y-W	6739
26111	7590	08/19/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			NASHED, NASHAAT T	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/987,455

Applicant(s)

MANOSROI ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 04 August 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 40-43, 45-56 and 58-60.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_



Nashaat T. Nashed, Ph. D.  
Primary Examiner  
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Continuation of 3. Applicant's reply has overcome the following rejection(s): under 35 USC 112, first and second paragraphs, and obviousness double patenting.

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The after-final amendment filed August 4, 2004 will be entered upon filing the appeal brief.

Upon entering the after-final amendment claims 40-43, 45-56, and 58-60 are pending.

The terminal disclaimer filed on August 8, 2004 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of any patent which may mature from copending application 09/987,457 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 40-56 and 58-60 are rejected under 35 U.S.C. 103 as being unpatentable over Wang *et al.* (IDS Document AM1: EP 0357391 A2) in view of Obukowicz *et al.* (IDS reference AR9: Biochemistry 1990, 29, 9737-9745), Niwa *et al.* [U. S. Patent 5,840,533 (533)] and the well known nucleic acid encoding human tissue plasminogen activator for the reasons set forth in the prior Office action mailed September 12, 2003, and the final rejection mailed May 4, 2004.

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Applicants continue to argue that none of the cited references teach the claimed invention because the references, when combined, must teach all the claims limitations and that the examiner has used improper hindsight in constructing the rejection.

Applicants' arguments filed 8/4/04 have been fully considered but they are not deemed to be persuasive. First, claim 40 from which claims 41-43, and 45-51 are dependent contains an intended use limitation; see the last three lines, which does not carry a patentable weight. The claimed nucleic acid of claim 40 has a specific structure laid out in (a)-(c) of claim 1. Thus, if the claimed product is anticipated or obvious, a new use for said product would not render the product patentable. Second, the examiner still in agreement with the applicants that none of the references teach the claimed invention, but he has met his burden in establishing a *prima facie* case of obviousness against the claims. Applicants should note that SEQ ID NO: 1 in the '533 patent is an amino acid sequence contains the amino acid sequences SEGN and SEGNSD when R is a serine residue; see the first line of column 3. In addition, the '533 patent discusses the signal peptide in a separate paragraph without specific reference to any particular cell or expression system. The use of signal peptide to secrete a recombinant protein from a host cell is well-established technology in the art. The '533 patent suggests and recommends the use of the signal peptide. Wong *et al.* teach the OmpA signal peptide and its use in the secretion of a recombinantly produced from *E. coli*. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).